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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/688,786 | 10/17/2003 | Henry R. Costantino | 1733.2025-003 | 9558 |

38421 7590 10/19/2005

ELMORE CRAIG & VANSTONE, P.C.
209 MAIN STREET
N. CHELMSFORD, MA 01863

EXAMINER

DESAI, ANAND U

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/688,786 | Applicant(s) COSTANTINO ET AL. | |
| | Examiner Anand U. Desai, Ph.D. | Art Unit 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31-35 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>20050726; 20050830</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on July 26, 2005. Claims 36-40 have been previously withdrawn as being drawn to a nonelected invention. Claims 1-35 are currently pending and are under examination.

Maintenance of Objection and Rejections

Claim Objections

2. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 5-17, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (U.S. Patent 6,749,866 B2) in view of Lee and Timasheff (Journal of Biological Chemistry Vol. 256, No. 14, pp. 7193-7201 (1981)).

5. Claims 3, 4, 18, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (U.S. Patent 6,749,866 B2) in view of Lee and Timasheff (Journal of Biological Chemistry Vol. 256, No. 14, pp. 7193-7201 (1981)) as applied to claims 1, 2, 5-17, and 19-22 above, and further in view of Taylor, K. et al. (Diabetes 51 (suppl. 2):85 Jun 2002).

6. Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (U.S. Patent 6,749,866 B2) in view of Lee and Timasheff (Journal of Biological Chemistry

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Vol. 256, No. 14, pp. 7193-7201 (1981)) as applied to claims 1, 2, 5-17, and 19-22 above, and further in view of Silvestri et al. (U.S. Patent 5,126,147).

7. Claims 1, 2, 5-17, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woiszwilllo et al. (U.S. Patent 5,981,719) in view of Bernstein et al. (U.S. 6,749,866 B2).

The teachings of the references in the 35 U.S.C. 103(a) rejections are disclosed in the office action mailed February 1, 2005.

Response to Applicant's Remarks

Applicants state the Patent Office has failed to present a *prima facie* case of obviousness. Applicants state "that light of the Patent Office's failure to identify any suggestion to combine within the cited references in an attempt to obtain the presently claimed inventions necessarily and inevitably requires the application of impermissible hindsight." Applicants state, "the Office Action has failed to point to any objective evidence of a motivation to combine or reasonable expectation of success within the cited references themselves."

Applicant's arguments filed July 26, 2005 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the references do disclose the knowledge generally available to one of ordinary skill in the art. The art discloses that manufacturing a sustained release composition comprising a biocompatible polymer, and a biologically active polypeptide requires the stabilization of a protein pharmaceutical agent. The references do disclose the stabilization of proteins comprising either a salt (see Bernstein et al.) or a sugar such as sucrose (see Lee and Timasheff). Therefore, a person having ordinary skill in the art would have been motivated to use both the sugar and the salt to increase the stability of the protein in the sustained release composition. Furthermore, the state of the art discloses the manufacturing of sustained release compositions comprising a biocompatible polymer and biologically active polypeptides, which are stabilized with either a salt (see Bernstein et al.) or a sugar such as sucrose (see Woiszwillo et al.). Thus, a person having ordinary skill in the art would have expected to succeed in manufacturing a sustained release composition comprising both a salt and a sugar, since both the salt and the sugar are known to stabilize the protein. Applicant is referred to MPEP 2144.06 "Art Recognized Equivalence for the Same Purpose COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows

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logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.)."

Conclusion

8. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

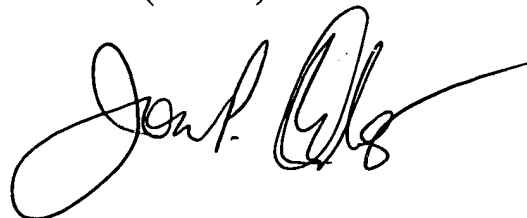
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 12, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER